

AO 120 (Rev. 3/04)

<b>TO:</b> <b>Mail Stop 8</b> <b>Director of the U.S. Patent and Trademark Office</b> <b>P.O. Box 1450</b> <b>Alexandria, VA 22313-1450</b>	<b>REPORT ON THE</b> <b>FILING OR DETERMINATION OF AN</b> <b>ACTION REGARDING A PATENT OR</b> <b>TRADEMARK</b>
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been  
filed in the U.S. District Court Delaware on the following ☒ Patents or ☐ Trademarks:

DOCKET NO. 07cv204	DATE FILED 4/17/07	U.S. DISTRICT COURT DISTRICT OF DELAWARE
PLAINTIFF MedPointe Healthcare Inc.		DEFENDANT Apotex Inc.; Apotex Corp.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1      5,164,194	11/17/92	Asta Pharma AG
2		
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading		
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK	
1			
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3			
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5			

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT <i>Case Closed 4-21-08 per findings of fact &amp; Content Judgment &amp; Order.</i> <i>See Attached</i>
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CLERK PETER T. DALLEO, CLERK OF COURT	(BY) DEPUTY CLERK <i>[Signature]</i>	DATE <i>4-21-08</i> April 18, 2007
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Copy 1—Upon initiation of action, mail this copy to Director    Copy 3—Upon termination of action, mail this copy to Director  
Copy 2—Upon filing document adding patent(s), mail this copy to Director    Copy 4—Case file copy

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MEDA PHARMACEUTICALS INC.,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

Civil Action No. 07-204-SLR

## **FINDINGS OF FACT AND CONSENT JUDGMENT AND ORDER**

The Court, upon the consent and request of Plaintiff, Meda Pharmaceuticals Inc., formerly known as MedPointe Healthcare Inc. ("Meda"), and Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), hereby makes the following Findings of Fact and issues the following Consent Judgment and Order:

## FINDINGS OF FACT

1. This Court has subject matter jurisdiction over this patent infringement action (the "Action") and personal jurisdiction over all of the parties to the Action. Venue is proper in this Court as to all parties to the Action.

2. In this Action, Meda has charged Apotex with infringement of United States Patent No. 5,164,194 ("the '194 Patent") in connection with Apotex's submission of Abbreviated New Drug Application ("ANDA") 78-621 directed to a generic azelastine hydrochloride ophthalmic solution to the U.S. Food and Drug Administration ("FDA").

3. In response to Meda's charge of patent infringement, Apotex has alleged certain defenses and counterclaims, including that the '194 Patent is invalid, unenforceable and not infringed by the generic azelastine hydrochloride ophthalmic solution defined by ANDA 78-621.

4. The claims, defenses and counterclaims in this action were scheduled for trial beginning on February 23, 2009.

5. Apotex has not rebutted the statutory presumption that the '194 Patent is valid and enforceable in this Action. This admission, however, is without prejudice to Apotex's allegations that the asserted claims of the '194 patent are invalid and unenforceable.

6. Apotex admits that the submission of ANDA 78-621 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of a generic azelastine hydrochloride ophthalmic solution, the use of which is claimed in the '194 Patent, within the United States before the expiration of the '194 Patent is an act of patent infringement. This admission, however, is without prejudice to Apotex's allegations that the asserted claims of the '194 patent are invalid and unenforceable.

7. Apotex has agreed that each of the defenses and counterclaims set forth in Defendants Apotex Inc.'s And Apotex Corp.'s Answer, Defenses and Counterclaims in this Action, including the allegations and averments contained therein, should be dismissed, without prejudice.

#### **CONSENT JUDGMENT AND ORDER**

Accordingly, pursuant to the above Findings of Fact, and upon the consent and request of Meda and Apotex, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA 78-621 was a technical act of infringement of the '194 Patent under 35 U.S.C. § 271(e)(2)(A).

2. Apotex's defenses and counterclaims with respect to the '194 Patent are hereby dismissed, without prejudice.

3. Apotex, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic azelastine ophthalmic solution defined by ANDA 78-621 during the life of the '194 Patent, including any extensions and pediatric exclusivity, absent authorization by Meda, unless all of the claims of the '194 Patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken.

4. Meda and Apotex each expressly waives any right to appeal or otherwise move for relief from these Findings of Fact and Consent Judgment and Order.

5. This Court retains jurisdiction over Meda and Apotex for purposes of enforcing these Findings of Fact and Consent Judgment and Order.

6. These Findings of Fact and Consent Judgment and Order shall finally resolve this Action between Meda and Apotex. Each party shall bear its own fees and costs in connection with this action, including attorney fees.

7. The Clerk of the Court is directed to enter this final judgment forthwith.

**SO ORDERED:**

This 21<sup>st</sup> day of April, 2008

A handwritten signature in black ink, appearing to read "Sue L. Robinson", is written over a horizontal line.

HONORABLE SUE L. ROBINSON  
UNITED STATES DISTRICT JUDGE